IN THE CLAIMS:

1. (Currently Amended) A method for the treatment of nonalcoholic steatohepatitis comprising:

administering a pharmaceutically acceptable formulation for oral administration to a human in need thereof wherein the formulation is comprised of:

a dietary ~~lecithin~~ supplement comprising lecithin in a form for oral ingestion,

a vitamin B complex, and

an antioxidant.

2. (Previously Presented) The method of claim 1 wherein the dietary lecithin supplement is comprised of a granulated phospholipid fraction of soya lecithin containing at least 50% phosphatidylcholine, at least 5% lysophosphatidylcholine and no more than 30% phosphatidylethanolamine.

3. (Currently Amended) The method of claim 1 wherein the vitamin B complex ~~is comprised of a combination of~~ contains at least two or more compounds selected from the group consisting of vitamin B-1, vitamin B-2, vitamin B-3, vitamin B-5, vitamin B-6, vitamin B-7, and vitamin B-12 and combinations thereof.

4. (Previously Presented) The method of claim 1 wherein the antioxidant is comprised of vitamin C.

5. (Previously Presented) The method of claim 1 wherein the antioxidant is comprised of vitamin E.

6. (Currently Amended) The method claim 1 wherein the antioxidant is comprised of selenium yeast containing bioavailable selenium as the antioxidant.

7. (Previously Presented) The method of claim 1 wherein the step of administering the formulation for oral administration is comprised of administering between approximately 15 to 50 grams.

8. (Previously Presented) The method of claim 1 wherein the dosage of the combination of the antioxidant and the B vitamin complex is between approximately 675 to 4050 milligrams.

9. (Previously Presented) The method of claim 1 wherein the formulation for oral administration is prepared as a daily dosage of approximately 20 grams of lecithin and 1350 milligrams of the comination of antioxidants and B vitamin complex.

10. (Previously Presented) The method of claim 1 wherein the formulation further comprises vitamin A.

11. (Previously Presented) The method of claim 1 wherein the formulation further comprises folic acid.

12. (Previously Presented) The method of claim 1 wherein the pharmaceutically acceptable formulation for oral administration comprises a pill.

13. (Previously Presented) The method of claim 1 wherein the pharmaceutically acceptable formulation for oral administration comprises a liquid.

RESPONSE

Claims 1-13 are currently pending in the action. The Examiner raises certain questions regarding the phraseology of claim 1, 3, and 6 under 35 U.S.C. § 112, 2d ¶. These comments and the accompanying claim amendments clarify each question raised by the Examiner.

The phrase "a dietary lecithin supplement" in claim number 1 is a form of a dietary supplement containing lecithin and which is suitable for oral ingestion. As reflected in the specification of the present invention, the lecithin supplement refers to a conventional dietary lecithin supplement, most frequently formed from a composition of phosphatidylcholine, phosphatidylethanolamine, lysophosphatidylcholine, and other phospholipids. Lecithin supplements are known generally in the art, apart from the present clinical indication as claimed, and their composition is well known. To resolve any ambiguity on this issue in the pending claims, Applicants have amended the claim to recite the fact that the "dietary lecithin supplement" can be alternatively described as "a dietary supplement comprising lecithin in a form for oral ingestion."

Referring to the phrase "vitamin B complex" in claim 1 and the Markush group in claim 3, the recitation in the claims is not inconsistent. A "vitamin B complex" is defined in the specification as a combination of two or more compounds from the entire vitamin B group. Claim 3 specifies that the vitamin B complex is two or more of a select subgroup of all possible vitamin B compounds. It is not believed that the use of the phrase "two or more" in claim 3, together with a similar recitation in the portion of the specification defining the "vitamin B complex" raises any significant ambiguity. However, Applicants have revised the claim to eliminate any possible ambiguity and to specify that the particular vitamin B compounds recited in claim 3 are merely selected members of the larger overall class of compounds that could be defined as within the phrase "vitamin B complex" in claim 1.

Similarly, the recitation of folic acid in claim 11 is consistent with the overall definition of the "vitamin B complex." The vitamin B complex contains individual members of the overall family of vitamin B compounds, which may include folic acid, but does not necessarily do so, in the broadest iteration of the claim as recited in claim 1. Dependent claim 11 simply specifies that the particular vitamin B complex defined by claim 11, read in combination with independent claim 1, necessarily includes the folic acid.

With respect to the phrase "selenium yeast" in claim 6, the phrase is commonly used in the field to describe a form of yeast used as a dietary supplement that contains intracellular selenium for nutritional purposes. Although this a well-recognized term of art, and would be properly understood by one of ordinary skill, Applicants have revised the claim for clarity. Specifically, the yeast is specified to be a yeast composition that contains bioavailable selenium as the antioxidant described in the independent claim 1.

Applicants submit that each § 112 clarification sought by the Examiner has been resolved by the foregoing amendments.

Applicants have also submitted a terminal disclaimer with respect to claims 1-6 of U.S. Patent No. 6,180,139. The terminal disclaimer, together with the foregoing clarifications under § 112, resolve each outstanding basis for rejection of the pending claims. Accordingly, Applicants submit that the application is in condition for allowance and requests such action accordingly.

The Commissioner is authorized to charge Orrick Herrington & Sutcliffe's Deposit Account No. **150665** in the amount of **$510.00** for the three-month extension fee (small entity) and authorized to charge any additional fees required by the filing of these papers, and to credit any overpayment to Orrick Herrington & Sutcliffe's Deposit Account No. **150665.**

Respectfully submitted,

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